

App. No: 09/164,862

Page 2

AMENDMENTS TO THE CLAIMS

Claim 1 (Previously presented): A method for estimating survival expectancy of a cancer patient, said method comprising:

(a) obtaining a biological sample comprising YKL-40 from a cancer patient having at least a preliminary diagnosis of a cancer selected from the group consisting of a lung cancer, a bronchus cancer, a colorectal cancer, a prostate cancer, a pancreas cancer, a stomach cancer, an ovarian cancer, a urinary bladder cancer, a brain or central nervous system cancer, a peripheral nervous system cancer, an esophageal cancer, a cervical cancer, a melanoma, a uterine or endometrial cancer, a cancer of the oral cavity or pharynx, a liver cancer, a kidney cancer, a biliary tract cancer, a small bowel or appendix cancer, a salivary gland cancer, a thyroid gland cancer, an adrenal gland cancer, an osteosarcoma, a chondrosarcoma, a liposarcoma, a testes cancer, and a malignant fibrous histiocytoma; and

(b) measuring the level of YKL-40 in said sample and comparing the sample YKL-40 level to the YKL-40 level found in the same sample from normal healthy humans wherein a sample YKL-40 level in excess of YKL-40 levels in the same sample from said normal healthy humans is an indicator of a reduced survival expectancy compared to patients with normal YKL-40 level.

Claim 2 (Original): The method of claim 1, wherein said patient has a diagnosis of prostate cancer.

Claim 3 (Original): The method of claim 1, wherein said patient has a diagnosis of lung cancer.

Claim 4 (Original): The method of claim 1, wherein said patient has a diagnosis of a colorectal cancer.

Claim 5 (Original): The method of claim 4, wherein said patient is diagnosed with a Duke's stage A colorectal cancer.

Claim 6 (Original): The method of claim 4, wherein said patient is diagnosed with a Duke's stage B colorectal cancer.

App. No: 09/164,862

Page 3

Claim 7 (Original): The method of claim 4, wherein said patient is diagnosed with a Duke's stage C colorectal cancer.

Claim 8 (Original): The method of claim 4, wherein said patient is diagnosed with a Duke's stage D colorectal cancer.

Claim 9 (Original): The method of claim 1, wherein said biological sample is a primary tumor or a tissue affected by the cancer.

Claim 10 (Original): The method of claim 1, wherein said biological sample is a sample selected from the group consisting of whole blood, plasma, serum, synovial fluid, cerebrospinal fluid, bronchial lavage, ascites fluid, bone marrow aspirate, pleural effusion, urine, and tumor tissue.

Claim 11 (Original): The method of claim 1, wherein the level of YKL-40 is measured by immunohistochemical staining of cells comprised within said biological sample.

Claim 12 (Original): The method of claim 11, wherein said cells are tumor tissue cells.

Claim 13 (Original): The method of claim 1, wherein the level of YKL-40 is measured using an immunoassay.

Claim 14 (Original): The method of claim 13, wherein said immunoassay is a competitive immunoassay.

Claim 15 (Original): The method of claim 13, wherein said immunoassay is an ELISA.

Claim 16 (Original): The method of claim 13, wherein said immunoassay is a radioimmunoassay (RIA).

Claim 17 (Original): The method of claim 13, wherein said immunoassay uses a polyclonal anti-YKL-40 antibody.

Claim 18 (Original): The method of claim 13, wherein said immunoassay uses a monoclonal anti-YKL-40 antibody.

App. No: 09/164,862

Page 4

Claims 19-37 (Canceled).

Claim 38 (Previously presented): A method to screen for recurrence of a cancer after removal of a primary tumor, said method comprising:

(a) obtaining a biological sample comprising YKL-40 from a cancer patient following removal of a primary tumor selected from the group consisting of a lung cancer, a bronchus cancer, a colorectal cancer, a prostate cancer, a pancreas cancer, a stomach cancer, an ovarian cancer, a urinary bladder cancer, a brain or central nervous system cancer, a peripheral nervous system cancer, an esophageal cancer, a cervical cancer, a melanoma, a uterine or endometrial cancer, a cancer of the oral cavity or pharynx, a liver cancer, a kidney cancer, a biliary tract cancer, a small bowel or appendix cancer, a salivary gland cancer, a thyroid gland cancer, an adrenal gland cancer, an osteosarcoma, a chondrosarcoma, a liposarcoma, a testes cancer, and a malignant fibrous histiocytoma; and

(b) measuring a level of YKL-40 in said sample and comparing the sample YKL-40 level to the YKL-40 level found in normal controls wherein a sample YKL-40 level in statistically significant excess of YKL-40 levels in normal controls is an indicator of a possible recurrence of said cancer.

Claim 39 (Original): The method of claim 38, wherein said method is repeated at a multiplicity of instances after removal of said primary tumor.

Claims 40-46 (Canceled).

Claim 47 (Currently amended): ~~In a differential diagnosis of a~~ a method of screening for an indicator for the presence of cancer, in a mammal, said method comprising:

(a) obtaining a biological sample comprising serum comprising YKL-40 from said mammal;

(b) measuring the level of YKL-40 in said ~~sample~~ serum and comparing the level to the YKL-40 level found in ~~the same samples~~ serum from normal healthy mammals, wherein a statistically significant ~~difference~~ elevation in YKL-40 level in the sample being tested compared to the sample from normal healthy mammals wherein said elevation is unrelated to known causes of YKL-40 elevation other than cancer, is an indicator of the presence of a cancer selected from the group consisting of a lung cancer, a bronchus cancer, a prostate cancer, a pancreas cancer, a stomach cancer,

App. No: 09/164,862

Page 5

an ovarian cancer, a urinary bladder cancer, a brain or central nervous system cancer, a peripheral nervous system cancer, an esophageal cancer, a cervical cancer, a melanoma, a uterine or endometrial cancer, a cancer of the oral cavity or pharynx, a liver cancer, a kidney cancer, a biliary tract cancer, a small bowel or appendix cancer, a salivary gland cancer, a thyroid gland cancer, an adrenal gland cancer, an osteosarcoma, a chondrosarcoma, a liposarcoma, a testes cancer, and or a malignant fibrous histiocytoma.

Claim 48 (Canceled).

Claim 49 (Currently amended): The method of claim 47, wherein said biological sample is a sample selected from the group consisting of whole blood, plasma, and serum, ~~synovial fluid, cerebrospinal fluid, bronchial lavage, ascites fluid, bone marrow aspirate, pleural effusion, urine, and tumor tissue.~~

The method of claim 47, wherein said biological sample is a sample selected from the group consisting of whole blood, plasma, and serum.

Claims 50-55 (Canceled).

Claim 56 (Original): The method of claim 47, wherein said mammal is a human.

Claim 57 (Original): The method of claim 47, wherein the level of YKL-40 is measured using an immunoassay.

Claim 58 (Original): The method of claim 57, wherein said immunoassay is a competitive immunoassay.

Claim 59 (Original): The method of claim 57, wherein said immunoassay is an ELISA.

Claim 60 (Original): The method of claim 57, wherein said immunoassay is a radioimmunoassay (RIA).

Claim 61 (Original): The method of claim 57, wherein said immunoassay uses a polyclonal anti-YKL-40 antibody.

App. No: 09/164,862

Page 6

Claim 62 (Original): The method of claim 57, wherein said immunoassay uses a monoclonal anti-YKL-40 antibody.

Claim 63 (Previously presented): The method of claim 13, wherein said immunoassay comprises immunohistochemical staining.

Claim 64 (Previously presented): The method of claim 38, wherein the level of YKL-40 is measured using an immunoassay.

Claim 65 (Previously presented): The method of claim 63, wherein said immunoassay comprises immunohistochemical staining.

Claim 66 (Previously presented): The method of claim 47, wherein the level of YKL-40 is measured using an immunoassay.

Claim 67 (Previously presented): The method of claim 65, wherein said immunoassay comprises immunohistochemical staining.